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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,956	11/30/2001	Zairen Sun	9U 301 R1	2406
26400	7590	04/02/2004	EXAMINER	
ORIGENE TECHNOLOGIES, INCORPORATED 6 TAFT COURT SUITE 100 ROCKVILLE, MD 20850			UNGAR, SUSAN NMN	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,956	SUN ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 February 2004 and 02 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-3,5-13,15-18 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) 4-13,15-17 and 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The Amendment filed February 13, 2004 and the Declaration filed March 2, 2004 in Response to the Office Action mailed October 14, 2003 are acknowledged and have been entered. Previously pending claims 1-3 have been amended. Claims 1-3 and 18 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant again traverses the restriction requirement which was made Final in the Office Action mailed October 14, 2003 and essentially reiterates arguments previously presented. The arguments have been considered and have not been found persuasive for the reasons previously set forth.
4. The following objections are maintained:

Objection to the specification recited on page 3 of the Paper mailed October 14, 2003 is maintained. Correction was not made and Applicant has not presented any arguments as to why they should not be made.

5. The following rejections are maintained:

Claim Rejections - 35 USC § 101

6. Claims 1-3 and 18 remain rejected under 35 USC 101 for the reasons previously set forth in the Paper mailed October 14, 2003, Section 5, pages 3-8.

Applicant argues that the Sun Declaration provides evidence that Pr33a is exquisitely and selectively expressed in prostate and not in 23 other tissues surveyed and this data is supported in the specification and tissue specificity is an adequate showing of utility. Applicant points to the Revised Interim Utility Guidelines Training Materials Example 12 wherein a marker that is specific for cancer has utility and cancer is a type of tissue, and further argues that there is no reason why tissue specificity of normal tissue

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would not have analogous utility. The argument has been considered but has not been found persuasive. A review of Example 12 reveals that the Example is drawn to a putative invention that analysis demonstrates does not have utility. The Example concludes with a Caveat wherein it is shown that a difference in a parameter, that is, differential expression on a cancer cell compared to a normal cell, imparts utility to the exemplified invention. However, unlike Example 12, the instant invention is not specific for a normal tissue, rather it is selective for that tissue and it has not been shown to be differentially expressed on a cancer cell when compared with a normal cell. Although the specification teaches that the polynucleotide is differentially expressed in prostate cancer, as previously set forth, there is no demonstration of that differential expression, no teaching of what control is used to determine the differential, no teaching of whether it is overexpressed, underexpressed or expressed in a different compartment, expressed in mutated form. If the instant invention is differentially expressed in prostate cancer as compared to normal control, it is unclear why Applicant argues, and the Sun Declaration supports, the selective expression of the instant invention in prostate as compared to other tissues. Why has Applicant chosen not to demonstrate a specific asserted utility, disclosed on page 1 of the specification, that the Guidelines specifically teach would overcome the finding of a lack of utility? Given Applicant's arguments, it would appear that the claimed invention is not differentially expressed in prostate cancer. Further, even if it had been shown that the claimed invention is differentially expressed in prostate cancer, differential expression in prostate cancer would not be a substantial utility because further work is required in order to determine whether it is upregulated,

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downregulated, mutated, in a different compartment as previously set forth. Further, the reasons why the claimed invention does not have specific utility were clearly set forth in the previous Action. In particular, its selective expression in prostate compared to other tissues also applies to many unrelated polynucleotides (see page 6 of the Paper Mailed October 14, 2003) for the reasons of record and thus the claimed invention does not have a specific utility.

Applicant further argues that it is not clear why the tissue selectivity of other prostate polynucleotides is relevant to the instant rejection. Applicant argues that (a) the utility of PSA is unrelated to its function but depends on tissue specificity and thus prostate specific markers therefore have a recognized commercial utility, (b) because of its tissue specificity, Pr33 can be used as a marker in biopsies to detect the presence of prostate tissue and to detect metastatic cells, (c) the rejection is illogical and counter to the policy reasons behind the establishment of the US Patent system, Applicant's discovery of a polynucleotide specifically expressed in prostate is precisely the type of useful invention the Patent Office was created to reward, the fact that other markers have been shown to be prostate tissue-specific is not any ground to question the utility of the claimed invention, (d) many drug targets have multiple ligands wherein each ligand has the same receptor specificity and each possesses substantial utility as evidenced by a commercial market replete with drugs that target the same receptors..

The arguments have been considered but have not been found persuasive because (a') unlike the instantly claimed invention, and identical to the Caveat discussion of Example 12 of the Guidelines, PSA is a characterized prostate tumor marker, (b') Pr33 is not tissue specific, rather it

is tissue selective and for the reasons of record the tissue selectivity of Pr33 does not impart a specific utility, its expression is not unique to prostate tissue, (c') although Applicant states that the fact that other markers have been shown to be prostate tissue-specific is not any ground to question the utility of the claimed invention, for the reasons of record, the fact that other markers have been shown to be prostate tissue-specific is relevant and because of this fact, the claimed invention does not have specific utility, (d') Applicant's argument is not relevant to the claimed invention, its ligands are unknown, it is unknown whether it is associated with any disease or what effect, if any, a drug would have on the claimed invention or the treatment of any disease. For the reasons of record, the claimed invention does not have a specific utility, a substantial utility, a well established utility and thus the credibility of the claimed invention cannot be assessed. Applicant's arguments have been considered but have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

7. Claims 1-3 and 18 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the Paper mailed October 14, 2003, Section 7, page 9.

Applicant argues that the claims have been amended to recite complements to the recited sequences are 100% identical thereto. The argument has been considered but have not been found persuasive because claim 18 has not been so amended.

8. Claim 1-3 and 18 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the Paper mailed October 14, 2003, Section 8, pages 9-14.

Applicant argues that the claims have been amended to recite complements to the recited sequences are 100% identical thereto. The argument has been considered but have not been found persuasive because claim 18 has not been so amended.

9. Claim 18 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the Paper mailed October 14, 2003, Section 9, pages 14-15.

Applicant argues that the claims have been amended to recite complements to the recited sequences are 100% identical thereto. The argument has been considered but have not been found persuasive because claim 18 has not been so amended.

10. Claim 18 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the Paper mailed October 14, 2003, Section 10, pages 15-17.

Applicant argues that the claims have been amended to recite complements to the recited sequences are 100% identical thereto. The argument has been considered but have not been found persuasive because claim 18 has not been so amended.

11. Claims 2-3 and 18 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the Paper mailed October 14, 2003, Section 11, pages 17.

Applicant argues that (a) there is no requirement that the specification provide *ipsis verbis* description of the claims and cites *In re Wertheim*, 191 USPQ, 90, 98 (CCPA 1976) wherein the claims were drawn to solids content ranging between 35% and 60% and cites *In re Lukach*, (b) the specification discloses a large number of sequence positions that fall within

the 5217 nucleotides of SEQ ID NO:1 and applicant was in possession of not only the specific fragments of Pr33a identified in the application but any intermediary fragments with its complete sequence and under the same reasoning set forth in *Wertheim*, applicant should be entitled to claim the narrower range within the broadly disclosed sequence.

The arguments have been considered but has not been found persuasive because (a')(b') since *In re Wertheim* is drawn to a non analogous art and Applicant has not explained its relevance or the relevance, or issues, in *In re Lukach* to the instantly claimed invention, the claimed invention is not supported by the suggested case-law. Further, there is no disclosure of or suggestion of the claimed ranges in the specification as originally filed, (b') a review of the cited support reveals support for (1) degenerative sequences, antisense, fragments of SEQ ID NO:1, (2) a genomic sequence related to SEQ ID NO:1 wherein multiple splice acceptor sites are disclosed and wherein multiple alternatively-spliced transcripts are detected, (3) disclosure of introns and exons, and (4) primers, but no support for the invention as currently claimed. The suggested support is not persuasive because nowhere in the suggested support is there support for the currently claimed invention. The subject matter claimed in claims 2, 3 and 18 broadens the scope of the invention as originally disclosed in the specification.

Claim Rejections - 35 USC § 102

12. Claim 18 remain rejected under 35 USC 102 (b) for the reasons previously set forth in the Paper mailed October 14, 2003, Section 13, page 18.

Because Applicant did not distinctly and specifically point out the supposed errors in the rejection, the rejection maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

13. Claim 1 is rejected under 35 USC 112, first paragraph as the specification does not contain a written description of the claimed invention. The limitation of "complements 100% identical thereto" has no clear support in the specification and the claims as originally filed. A review of the specification did not reveal any mention of complements that are 100% identical to SEQ ID NO:1 or a polynucleotide comprising SEQ ID NO:1. It is noted that complements that are 100% identical to SEQ ID NO:1 would have a sequence that is identical to SEQ ID NO:1 and therefore would not be complements of SEQ ID NO:1.

14. Claim 1 is rejected under 35 USC 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the claimed invention.

The claim is drawn to a complement 100% identical to SEQ ID NO:1 or a polynucleotide comprising SEQ ID NO:1. Since a complement is by definition a polynucleotide that will hybridize to another polynucleotide and since complementarity is required for that binding and the claimed complement is 100% identical to SEQ ID NO:1 or a polynucleotide comprising SEQ ID NO:1, one would not know how to make the claimed invention.

15. All other objections and rejections recited in Paper No. 10 are hereby withdrawn.

16. No claims allowed.

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17. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P.

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

18. Any inquiry concerning this communication or earlier communications from

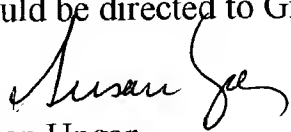
the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

A handwritten signature in cursive script, appearing to read "Susan Ungar".

Susan Ungar
Primary Patent Examiner
March 29, 2004